COMMENTARY

Health Care Reform Bill Expands Access to Section 340B Discounted Drugs for Hospitals

Stephen Barlas

Many hospital pharmacy directors around the country are rubbing their hands together hungrily, ready to dig in to the federal 340B Drug Pricing Program as if it were a Thanksgiving Day feast. The program provides federally designated health clinics and so-called safety net hospitals access to deeply discounted drug prices.

Two recent developments make the program, which has been around since 1992, an even juicier repast. First, the Health Care Reform Bill, known as the Patient Protection and Affordable Care Act (PPACA), which Congress passed in March 2010, contained first-time access to discounted 340B drugs for five new categories of hospitals:

- critical access hospitals
- sole community hospitals
- rural referral centers
- free-standing children's hospitals
- free-standing cancer hospitals

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The Health Resources and Services Agency (HRSA), which administers Section 340B, held an expedited sign-up period for those hospitals from August 2 to September 27, 2010. Hospitals that didn't get their applications in during that period must wait until January 1, 2011, to apply.

HRSA Administrator Mary Wakefield, PhD, RN, says:

> We estimate that as many as 1,500 additional hospitals may now be eligible for discounted medications through the Affordable Care Act. In total, we believe the number of sites participating in the 340B program will rise from more than 14,000 to nearly 20,000 when you also factor in clinics and health centers that will be eligible.

Both newcomers and veteran participants will be able to buy larger quantities of 340B drugs, thanks to a new policy announced last March by the Office of Pharmacy Affairs (OPA) at the HRSA. The new rule allows all hospitals in the 340B program to extend sales of 340B drugs beyond their outpatient pharmacy and a limit of one retail location to numerous retail pharmacies. Hospitals, for the first time, will be allowed to sign agreements with retail pharmacy networks. The hospitals, in essence, would buy 340B drugs, stock the drugstore's inventory with them, and then handle reimbursements when hospital patients fill prescriptions at their local drugstore.

It is important to understand that the 340B program was developed to help safety net hospitals build their profits so that they could ably serve the community. Their patients, up until now, filled prescriptions at the hospital's outpatient pharmacy and the hospital billed the patient's insurance company for the full price of the drug, which it obtained at a 340B price, usually 25% to 40% of the average manufacturer's price (AMP). That differential goes into the hospital's pocket, totaling as much as $10 million per year for some larger hospital systems.

That dab of honey on the bottom line of a safety net hospital (or federal clinic) is especially sweet these days, with public hospitals beset by state cutbacks in Medicaid funding at the same time that their uncompensated care to low-income populations has increased. Last February, the National Association of Public Hospitals and Health Systems estimated that the increase in uncompensated care costs averaged more than $2.3 million per hospital; some hospitals incurred more than $16 million in additional costs. Not all public hospitals qualify as safety net hospitals, which must exceed a certain level of Medicaid recipients as a percentage of total patients—but all safety net hospitals are public hospitals.

Patients, however, are not the prime beneficiaries of 340B; hospitals are. Typically, these safety net hospitals are owned by the state, county, or city; they are the medical care options of last resort for the working poor. Pharmaceutical companies must make all of their drugs available at 340B prices if they wish to sell those same drugs to state Medicaid programs. Medicaid and 340B prices can differ, and the latter are based on complicated formulas, made more opaque by the fact that the drug manufacturers do not have to publish their 340B prices; moreover, the OPA does not make them available to hospitals. That is changing as a result of one provision of the PPACA.

To qualify for 340B drugs, a hospital must show on its Medicare Cost Report that it serves Medicaid patients at a rate of at least 25% (even though those Medicaid patients do not qualify for 340B drugs). This is called a Medicare "disproportionate share hospital" (DSH). The DSH adjustment must actually exceed 11.75%. The hospital must also be public (owned by a city, state or county). The hospital's outpatient pharmacy buys the discounted drugs and sells them to either Medicaid or working poor "patients"—hence the importance of this definition—for the 340B price. The hospital then bills the insurance company for the full price, pocketing the 340B discount.

Diana Bond, RPh, Director of Pharmaceutical Services at the University Medical Center of Southern Nevada (UMC), estimates that participation in the 340B drug program saves her hospital about $9 million each year. The center is smack-dab in the middle of Las Vegas, and owned by Clark County, an area served by three other hospital systems: two for-profit (Valley Health Systems with five hospitals and Hospital Corporation of America with three) and Catholic Health Care West, a not-for-profit but not a safety net hospital. UMC has 12 clinics in distant parts of far-flung Las Vegas Valley and Clark County. One clinic, two blocks from the hospital in downtown Las Vegas, has an outpatient pharmacy, as does the hospital.

Ms. Bond says, "The nine million we save annually because

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of 340B helps underwrite the entire system, our level 1 trauma center, neonatal level 3, the only burn unit that serves northern Nevada, plus California and our transplant unit."

The annual savings earned by UMC of Southern Nevada are more or less typical. Andrew Lowe, PharmD, Pharmacy Director at Arrowhead Regional Medical Center in Colton, Calif., says his hospital "earns" $11 million per year. Those savings, pocketed by the 800 DSHs (out of approximately 8,000 hospitals in the U.S.) and by federally qualified health clinics currently registered in the program, help explain why critical access hospitals, sole community hospitals, rural referral centers, and free-standing children's and free-standing cancer hospitals, all of which won first-time access by the PPACA, are salivating at the prospect of 340B enrollment. However, children's hospitals and cancer hospitals that obtain covered outpatient drugs through a group-purchasing organization (GPO) are not eligible for participation in the expanded 340B program.


Ted Slafsky

Although the 340B program smells like roses to the hospitals and thousands of federal clinics that were enrolled before the PPACA was passed, that law's opening of the door to the five new categories of covered entities came with a few thorns attached. In the version of the PPACA that Congress originally passed on March 23, 2010, the 340B provision extended access to all hospitals and contained no restrictions on drug categories that the new entrants would have access to. But between March 23 and March 28, Congress quickly wrote technical amendments to the PPACA, ostensibly correcting wording errors and confusing language—but not the substance—in the bill it had passed just six days earlier. However, the drug manufacturers, represented by the trade group Pharmaceutical Research Manufacturers of America (PhRMA), and the biotech manufacturers, represented by the Biotechnology Industry Organization (BIO), worked overtime during that six-day period. And presto—when the technical corrections bill was signed by President Barack Obama, it deleted access to inpatient pharmacies and excluded 350 orphan drugs from the list of 340B drugs available to the five categories of newly covered entities.

"That was an unpleasant surprise for 340B providers," says Ted Slafsky, Executive Director of Safety Net Hospitals for Pharmaceutical Access.

That orphan drug exclusion may douse the interest of some of the hospitals for which the 340B door has now swung open. Many of those excluded agents are expensive cancer drugs. Diana Bond says that when UMC entered the 340B program in 1994, the pharmacy saw a drop of 75% in the cost of cancer drugs in the first year. Without that big-ticket discount, the nation's 11 free-standing cancer centers in the U.S. would think twice about entering 340B. As it happens, only one center has a high enough DSH percentage to qualify for 340B—the City of Hope Hospital in Duarte, Calif., near Los Angeles.

Another facility with first-time access to 340B is Enumclaw Regional Hospital, in the state of Washington, located in the foothills of the Cascades Mountains. This critical access hospital, defined as having fewer than 25 beds, is the only hospital around for miles. Enumclaw jumped at the opportunity to get 340B prices and was accepted by HRSA about two weeks after applications were allowed to be submitted. It was able to move quickly because the Franciscan Health System in the state had been dealing with 340B with three of five hospitals such as St. Joseph Medical Center.

Michael Bonck, RPh, Pharmacy Manager of Franciscan Health System and chairman of the institutional review board, and his colleagues quickly submitted an application for Enumclaw, which was approved. The outpatient pharmacy at Enumclaw is already contributing to the hospital's bottom line by saving money on drugs such as zoledronate (Reclast, Novartis), the once-yearly infusion for osteoporosis. However, Enumclaw's outpatient pharmacy will not be able to buy infliximab (Remicade, Centocor), for example, at 340B prices, and that hurts badly. Mr. Bonck says that infliximab, which has an indication for Crohn's disease and is on the list of 350 mostly expensive drugs not available at 340B prices to new participants, accounts for $280,000 in annual sales at Enumclaw, where it is primarily indicated for the treatment of rheumatoid arthritis and Crohn's disease.

"That is a huge value proposition loss for Enumclaw," he states, especially considering that infliximab constitutes about 23% of the hospital's total drug spending in a year. That is particularly galling, he adds, because orphan drug status is supposed to be awarded only to drugs with small markets, and Johnson & Johnson's (J&J's) sales of infliximab, which the FDA has also approved for ankylosing spondylitis, pediatric Crohn's disease, ulcerative colitis, psoriatic arthritis, and plaque psoriasis, are estimated to be $5.45 billion per year. Mr. Bonck and others are waiting for clarification from the OPA as to whether manufacturers have to make the 350 orphan drugs available at 340B prices for non-orphan indications.

Kassy McGourty, a spokesperson for J&J, says that infliximab and several other products do have approved orphan drug indications. She explains:

"However, the recently passed legislation poses a very complex situation. Like many health care companies, we're reviewing the situation and seeking guidance from HRSA and CMS. We hope to have a resolution in the next several weeks."

Although orphan drugs will not be available to newly minted 340B participants, the program's veterans have had problems in the past getting 340B prices on *clearly eligible* drugs. Michael Bonck says that patented drugs such as eptifibatide (Integrilin, Schering-Plough), used in percutaneous coronary intervention (PCI) procedures, and bivalirudin (Angiomax, The Medicines Company), used in coronary angioplasty, are very expensive and were hard to get at 340B prices up until about December 2009. The same situation applies to immunoglobulin (from companies such as CSL Behring, Baxter, Talecris, and Grifols), which is difficult to obtain consistently at 340B pricing.

"Companies will say there are shortages of the product, and you have to call and call and hit the right people," states Mr. Bonck.

Even when a hospital pharmacist can get an expensive drug at a 340B price, it isn't clear that the 340B price charged by the manufacturer is actually an accurate 340B price. The company does not have to publish 340B prices, which are proprietary—and as if that isn't non-transparent enough, the OPA

does not publish the price at which a particular 340B drug *should be sold*. So hospital pharmacists are in the dark about whether the price they pay, as well as the discount they receive, is correct. That has led to hospitals paying more than they should have. Both the Government Accounting Office (GAO) and the Office of the Inspector General (OIG) at the Department of Health and Human Services (DHHS), which houses the HRSA, have reported on that overpricing in detail during the past five years. The OIG estimated that 14% of total drug purchases made by facilities in June 2005 exceeded the 340B prices, resulting in $3.9 million in overpayments.

That problem led to a lawsuit, filed by Santa Clara County, Calif., against drug manufacturers, and was aimed at forcing them to open their 340B pricing files. At least one "transparency" provision in the PPACA stems from those overpricing reports and the Santa Clara lawsuit. The OPA is now required to establish a new system to compare the ceiling prices with actual pricing data submitted by manufacturers, to perform spot checks of sales transactions, and to take corrective action to address any identified pricing discrepancies.

Ted Slafsky says, "The requirement in health care reform for OPA to publish 340B prices in a password-protected Web site is a major development."

The PPACA also changes the way 340B prices are calculated, in two important but contradictory ways. However, Ted Slafsky says he is cautiously optimistic that the bottom line will mean lower 340B prices across the board. First, the AMP calculation is revised, resulting in what will generally be a higher price per drug. But the discount from the AMP price that results in the final 340B price will increase, from the current 15.1% to 23.1% for most brand-name prescription drugs, from 15.1% to 17.1% for brand-name pediatric drugs and clotting factors, and from 11% to 13% for generic and over-the-counter drugs. Manufacturers and wholesalers must offer even greater discounts on brand-name drugs if the manufacturer's best price for a drug is lower than the AMP minus 23.1% for that drug and if the price of the drug has increased faster than the rate of inflation. For example, if Pfizer sells a drug to Kaiser Permanente at a 32% discount off the AMP, it must offer the same price to 340B purchasers. In addition, hospitals are free to negotiate discounts that are lower than the manufacturer's 340B price through individual contracts, or they can go through the 340B Prime Vendor Program, run by Apexus Inc. This company receives volume discounts by aggregating the orders of 340B purchasers that don't have the buying clout of hospitals in large urban centers.

If working through Apexus is one way to increase hospital revenue, working through contract pharmacies or a contract pharmacy administrator is another. Prior to March 2010, when the OPA changed its policy, a hospital could contract with one pharmacy retailer who could provide 340B pricing to the hospital's eligible patients at one retail site. That obviously was a limited benefit to a hospital such as UMC of Southern Nevada, which serves Clark County, an area of 8,000-plus square miles and larger than the state of New Jersey, The OPA's green light to wider usage of contract pharmacies has led to safety net hospitals in the 340B program negotiating with companies such as Wellpartner, Inc., an Oregon-based company that assembles pharmacy networks in a hospital's service area.

Robert Judge, Executive Vice President and General Manager of Contract Pharmacy Services at Wellpartner, Inc., says his company collaborates with its hospital clients to set up a network of retail pharmacies strategically located to facilitate access for as many 340B-qualifying patients as possible. This process includes patient zip code mapping and linguistic compatibility to find the right neighborhood pharmacies to maximize community coverage.

Other companies around the country that offer a range of contract pharmacy administration services include SunRx, NEC Health, and Hudson Headwaters Health Solutions. In addition, retailers such as CVS, Walgreens, and Rite Aid are also scrambling to sign new 340B contracts with hospitals; however, in that latter instance, qualified hospital patients would have to use, for example, a CVS pharmacy for the hospital to be eligible for the 340B discount.

Not all contract pharmacy administrators are equal. One key thing to look for is an administrator that insures patients receiving 340B prices at retail are actually eligible. Sometimes this determination isn't obvious, and companies such as Wellpartner have sophisticated software systems to prevent diversion to ineligible customers. Wellpartner provides detailed reports to ensure its clients' 340B program conforms to strict federal requirements for both dispensing and replenishment. It is the 340B administrator who is responsible for replenishing drug inventories at retail locations. Inventories have to be replenished on time, and pharmacies are paid by the hospital for that replenishment, because the pharmacies typically use their own capital to buy 340B drugs.

Hospitals do have an alternative to a contract pharmacy relationship for reaching qualified patients in outlying areas who can't get to the hospital's outpatient pharmacy for a refill or if there is no outpatient pharmacy for the original prescription. Arrowhead Regional Medical Center in Colton, Calif., uses a company called OnTrac (formerly, California Overnight) to deliver prescriptions filled in its outpatient pharmacy to patients in outlying areas. "Split billing" is advantageous because it allows the hospital to order for both its inpatient and outpatient pharmacies and to get lower prices for both—even lower than the discounted 340B price for outpatient prescriptions—because of the combined volumes. On the other hand, the delivery cost per prescription can be higher than the administrative cost per prescription for using a contract pharmacy.

Andrew Lowe, PharmD, pharmacy director at Arrowhead, which is owned by San Bernardino County, says that his costs for filling patient refills is less expensive with OnTrac than with a contract pharmacy.

He says, "It would be more expensive to use a retail pharmacy because we would have to pay a filling fee and be responsible for the integrity of the drug distribution, including having to do audits. Diversion can be a big headache, and it doesn't happen when we use OnTrac."

Outpatient pharmacy use of delivery services and contract pharmacy networks to extend 340B pricing will help hospitals—both current 340B participants and the swarm of new ones—bleed off building financial pressure from their owners (i.e., cities, counties, and states) whose budgetary problems are forcing funding cutbacks at many of their public facilities, whether they be police departments or hospitals. ■